Apteryx, Inc.
Mark Gniewek
Regulatory Manager
313 S. High St., Suite 200
AKRON, OH 44308

November 30, 2018

Re: K182815
Trade/Device Name: XVWeb 3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 26, 2018
Received: October 3, 2018

Dear Mark Gniewek:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182815

Device Name
XVWeb 3D

Indications for Use *(Describe)*
XVWeb 3D is a Picture Archiving and Communications System (PACS) that enables dental facilities to query and access digitally stored hard and soft tissue intraoral /extraoral radiological images using an internet/web browser.

A web-based interface provides users the needed functionality to display patient images and studies in commercially available web browsers. Patient images/studies can be accessed by users locally within the system or across a wide-area network at distributed locations.

Acquisition can be included via integration with a DICOM-compatible Imaging and/or PACS system configured to forward images to the XVWeb 3D database. XVWeb 3D is compatible with programs that run on standard "off-the-shelf" personal computers, business computers, and servers running standard operating systems.

The system allows users to: manipulate (e.g. rotate, flip, etc.); enhance (e.g. increase or decrease brightness/contrast, gamma correction); add labels (e.g. measurements, lines, arrows, etc.), annotations to patient images/studies and other relevant operations for diagnostic purposes.

XVWeb 3D is designed for medium to large dental practices and is intended for trained dental professionals and technicians to access, manipulate, and enhance dental images for diagnostic purposes only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

7. 510(K) SUMMARY

1. Submitter Information

Contact: Mark Gniewek, Regulatory Manager
Apteryx, Inc.
313 S. High St., Suite 200
Akron, OH 44308
(330) 376-0889

Date Prepared: May 31, 2018

2. Device Name and Classification

Trade/proprietary name: XVWeb 3D
Common/usual name: 3D imaging, analysis, and diagnostic software
Classification name: PACS (21 CFR 892.2050, Product Code LLZ)
Regulatory Class: II

3. Manufacturer Address and Registration Number

Apteryx, Inc.
313 S. High St., Suite 200
Akron, OH 44308

FDA Registration Number: 3007350723

4. Predicate Device Information

The predicate device is XVWeb, K132342, date of concurrence: December 20, 2013.

5. Labeling and Intended Use

Labeling

No changes to the XVWeb labeling have occurred. For those who wish to add XVWeb 3D to their existing XVWeb workflow, Apteryx simply enables the 3D imaging module on the customer's existing XVWeb site when the purchasing process is complete.

The instructions for use can be found in the product's online documentation.

Intended Use

XVWeb 3D is a Picture Archiving and Communications System (PACS) that enables dental facilities to query and access digitally stored hard and soft tissue intraoral /extraoral radiological images using an internet/web browser. This is the **same intended use** as previously cleared for XVWeb, K132342.

6. Device Description

What it is

XVWeb 3D is an add-on software module for XVWeb (K132342) that enables dental practices to query and access digitally stored, 3D hard- and soft-tissue cone beam CT images using an internet/web browser. XVWeb 3D uses the web-based interface provided by XVWeb to display patient 3D images and studies.

XVWeb 3D allows users to manipulate 3D images an infinite number of ways, allowing the dental anatomy to be viewed from every possible perspective, providing the information needed to plan efficient treatments. XVWeb 3D also allows users to enhance images (e.g., increase or decrease brightness/contrast, gamma correction), and add measurement labels to 3D patient images/studies for diagnostic purposes, and view the image's DICOM information entities.

XVWeb 3D is designed for medium to large dental practices and is intended for trained dental professionals and technicians to access, manipulate, and enhance dental cone beam CT images of the teeth, jaw, and lower skull area for diagnostic purposes only. The patient population are those who have had a dental cone beam CT examination.

XVWeb 3D does not function by itself (i.e., it is not standalone software that can be launched and ran), it is integrated with XVWeb to query/access/view/ patient 3D images. XVWeb 3D is not required for XVWeb, it is an extra-cost option available to those who wish to add 3D-imaging capability to their existing XVWeb workflow. XVWeb 3D does not perform any radiographic image acquisition.

How it works

XVWeb 3D uses the DICOM file format standard to process the raw images/CT frames that have rescale type HU (Hounsfield unit) from the cone beam CT system. These files are sent from wherever the cone beam CT examination is taking place (i.e., the doctor's office, or "client") to the XVWeb DICOM server via web service. The DICOM files contain the raw images/CT frames in the form of parallel, horizontal slices of the head, starting from the bottom and proceeding to the top (i.e., the axial plane view).

When all of the CT frames for a given patient/series are received by the XVWeb DICOM server, a separate server, referred to as the 3D server, preprocesses the axial plane CT frames. This preprocessing consists of several steps:

- The spacing between each CT frame is computed
- The minimum and maximum pixel value in all CT frames is computed
- If necessary, frames are downscaled and/or merged to optimize them for web browser bandwidth and throughput
- Each CT frame is normalized using the minimum and maximum pixel values computed earlier
- Each CT frame is stored as a JPEG file on the customer's existing XVWeb site

When the preprocessing is complete, a user can then access the stored CT data using the XVWeb user interface in a web browser. One way the CT data will appear in the browser is as a series thumbnail image in the series bar on the left side of the XVWeb user interface. When the user clicks the CT thumbnail image, the browser begins to request the JPEG files created during the preprocessing steps. When all of the JPEG files are loaded into the browser, XVWeb 3D renders the orthogonal MPR slices (the axial, sagittal, and coronal plane views) and the 3D volume view and displays them in the XVWeb user interface. The user can then manipulate the 3D volume and slices using the controls within the XVWeb interface. XVWeb 3D also renders the

curved MPR slice (including cross-sectional slices) and makes it available for manipulation when the Curved MPR View button is clicked and a curve is drawn in the XVWeb interface. Cross-sectional slices related to the user-drawn curve are also rendered, but not until after the curve is drawn.

7. Indications for Use

XVWeb 3D is a Picture Archiving and Communications System (PACS) that enables dental facilities to query and access digitally stored hard and soft tissue intraoral /extraoral radiological images using an internet/web browser.

A web-based interface provides users the needed functionality to display patient images and studies in commercially available web browsers. Patient images/studies can be accessed by users locally within the system or across a wide-area network at distributed locations.

Acquisition can be included via integration with a DICOM-compatible Imaging and/or PACS system configured to forward images to the XVWeb 3D database. XVWeb 3D is compatible with programs that run on standard "off-the-shelf" personal computers, business computers, and servers running standard operating systems.

The system allows users to: manipulate (e.g. rotate, flip, etc.); enhance (e.g. increase or decrease brightness/contrast, gamma correction); add labels (e.g. measurements, lines, arrows, etc.), annotations to patient images/studies and other relevant operations for diagnostic purposes.

XVWeb 3D is designed for medium to large dental practices and is intended for trained dental professionals and technicians to access, manipulate, and enhance dental images for diagnostic purposes only.

8. Comparison

The only modification that was made to the originally-cleared device is the 3D data recognition, processing, and image manipulation capabilities within the XVWeb interface. These capabilities are contained in the add-on software module.

The XVWeb 3D module extends the cloud capability of XVWeb to include cone beam CT datasets, allowing 3D images of dental structures, soft tissues, nerve paths and bone in the human craniofacial region to be included in the XVWeb query/access/view/diagnose workflow.

Engineering drawings, schematics, etc. are not applicable to the device (figures are not pertinent to describe the differences between subject and predicate devices).

Substantial Equivalence

XVWeb 3D has the following similarities to the previously-cleared XVWeb:

- Same indicated use
- Ability to query and view patient images
- Ability to manipulate images (e.g., view from different perspectives, zoom in/out)
- Ability to enhance images (e.g., increase/decrease brightness, contrast, and gamma correction)
- Ability to add measurement labels
- Ability to view DICOM information entities (e.g., patient, study, series, image)
- Ability to export a copy of images

While XVWeb applied the above device characteristics to 2D images, XVWeb 3D allows these same characteristics to be applied to 3D images.

Software Verification and Validation Testing

XVWeb 3D verification and validation testing were conducted and documentation was provided, including pass/fail criteria, as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Apteryx believes the XVWeb 3D Level of Concern to be Moderate, since a latent design flaw could result in an erroneous diagnosis that would likely lead to minor injury.

Clinical Studies

No clinical testing was performed.

9. Conclusions

In summary, the XVWeb 3D module described in this submission is, in the opinion of Apteryx, substantially equivalent to the predicate device, XVWeb.